

Practitioner's Docket No. MPI90-002CP2DV1CNBCN3M

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Wolf, David L., et al		
Application No.:	10/712,332	Group No.:	1648
Filed:	November 13, 2003	Examiner:	N/A
For:	AGENTS AFFECTING THROMBOSIS AND HEMOSTASIS		

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT

**IDENTIFICATION OF TIME OF FILING THE ACCOMPANYING
INFORMATION DISCLOSURE STATEMENT**

The information disclosure statement submitted herewith is being filed:

☐ Within three months of the filing date of the application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 C.F.R. section 1.97(b).

OR

☐ *After* three months of the filing date of this national application or the date of entry of the national stage as set forth in Section 1.491 in an international application or after the mailing date of the first Office action on the merits, whichever event occurred last but *before* the mailing date of either:

CERTIFICATION UNDER 37 C.F.R. SECTIONS 1.8(a) and 1.10*

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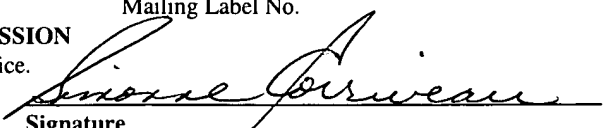
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Simonne Corriveau

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Date: March 9, 2004

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Practitioner's Docket No. MPI90-002CP2DV1CNBCN3M

- (1) a final action under Section 1.113,
- (2) a notice of allowance under Section 1.311, or
- (3) an action that otherwise closes prosecution in the application

whichever occurs first.

☐ Accompanying this transmittal is the fee set forth in 37 C.F.R. Section 1.17(p) for submission of an information disclosure statement under Section 1.97(c). (\$180.00).

☐ Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. 37 C.F.R. Section 1.97(e)(1).

☐ No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and to the knowledge of the person signing the statement after making reasonable inquiry, was known to any individual designated in Section 1.56(c) more than three months prior to the filing of the information disclosure statement. 37 C.F.R. Section 1.97(e)(2).

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☐ The information disclosure statement transmitted herewith is being filed *after* a final action under Section 1.113, or a notice of allowance under Section 1.311, whichever occurs first, but before, or simultaneously with, the payment of the issue fee.

☐ In accordance with the requirements of 37 C.F.R. Section 1.97(d):

A. ☐ Accompanying this transmittal is the fee set forth in 37 C.F.R. Section 1.17(p) for submission of an information disclosure statement under Section 1.97(c). (\$180.00).

B. ☐ Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. 37 C.F.R. Section 1.97(e)(1).

C. ☐ No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and to the knowledge of the person signing the statement after making reasonable inquiry, was known to any individual designated in Section 1.56(c) more than three months prior to the filing of the information disclosure statement. 37 C.F.R. Section 1.97(e)(2).

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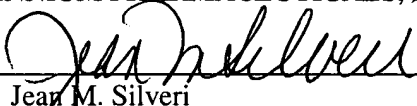
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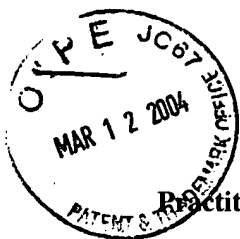
3. ☐ The fee due is set forth in 37 C.F.R. Section 1.17(p) for submission of an information disclosure statement under Section 1.97(c) (\$180.00).

☒ Applicant believes no fee is due in connection with this submission.

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METHOD OF PAYMENT OF FEE			
4. <input type="checkbox"/> Attached is a check in the amount of \$ _____.			
<input type="checkbox"/> Charge Account No. 501668 in the amount of		\$0.00	.
<input type="checkbox"/> A duplicate of this request is attached.			

If any additional fees are due, please charge Account 501668.

<u>March 9, 2004</u>	MILLENNIUM PHARMACEUTICALS, INC. By  Jean M. Silveri Registration No. 39,030 40 Landsdowne Street Cambridge, MA 02139 Telephone - 617-679-7336 Facsimile - 617-551-8820
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Applicant's Docket No. MPI90-002CP2DV1CNBCN3M

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Wolf, David L., et al
Application No.: 10/712,332 Group No.: 1648
Filed: November 13, 2003 Examiner: N/A
For: AGENTS AFFECTING THROMBOSIS AND HEMOSTASIS

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

List of Sections Forming Part of This Information Disclosure Statement

The following sections are being submitted for this Information Disclosure Statement:

1. ☒ Preliminary Statements
2. ☒ Forms PTO/SB/08A and 08B (substitute for Form PTO-1449)
3. ☒ Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted

Preliminary statements

Applicants submit herewith patents, publications or other information, of which they are aware that they believe may be material to the examination of this application, and in respect of which, there may be a duty to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. section 1.97(g)), an admission that the information cited is, or is

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considered to be, material to patentability, or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.

**Identification of Prior Application in Which Listed Information Was Already Cited and for Which
No Copies Are Submitted or Need Be Submitted**

This application relies, under 35 U.S.C. section 120, on the earlier filing date of prior application USSN.: 09/016,403, filed on January 30, 1998.

(complete the following, if applicable)

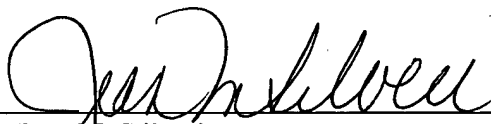
- (x) This application also relies, under 35 U.S.C. section 120, on the earlier filing dates of prior applications USSN 08/469,301, filed on June 6, 1995; USSN 08/268,003 filed June 29, 1994; and USSN 07/578,646 filed September 4, 1990.

The following references were submitted to, and/or cited by, the Office in the prior application(s) and, therefore, are not required to be provided in this application:

March 9, 2004

MILLENNIUM PHARMACEUTICALS, INC.

By



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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Complete if Known	
Sheet	1	of	1	Application Number	10/712,332
				Filing Date	November 13, 2003
				First Named Inventor	David L. Wolf et al.
				Group Art Unit	1648
				Examiner Name	N/A
				Attorney Docket Number	MPI90-002CP2DV1CNBCN3M

[illegible][illegible]

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¹Unique citation design number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁸Applicant is to place a check mark here if English language Translation is attached.

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		Application Number	10/712,332		
		Filing Date	November 13, 2003		
		First Named Inventor	David L. Wolf		
		Group Art Unit	1648		
		Examiner Name	N/A		
Sheet	1	of	4	Attorney Docket Number	MPI90-002CP2DV1CNBCN3M

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and-or country where published.	T ²
	B1	Hoover, R.L. et al., "The Adhesive Interaction between Polymorphonuclear Leukocytes and Endothelial Cells in vitro" <u>Cell</u> , (June, 1978) Vol. 14, No. 2 pp. 423-428.	
	B2	Etingin, O.R. et al., "Viral Activation of the Coagulation Cascade: Molecular Interactions at the Surface of Infected Endothelial Cells" <u>Cell</u> , (May 18, 1990) Vol. 61, No. 4 pp. 657-662.	
	B3	Furie, B. et al., "The Molecular Basis of Blood Coagulation" <u>Cell</u> , (May 20, 1988) Vol. 53, No. 4 pp. 505-518	
	B4	Di Scipio, R.G. et al., "Activation of Human Factor X (Stuart Factor) by a Protease from Russell's Viper Venom" <u>Biochemistry</u> , (November 29, 1977) Vol. 15, No. 24 pp. 5253-5260.	
	B5	Nesheim, M.E. et al., "The Contribution of bovine Factor V and Factor Va to the Activity of Prothrombinase" <u>The Journal of Biological Chemistry</u> , (November 10, 1979) Vol. 254, No. 21 pp. 10952-10962.	
	B6	Nasheim, M.E. et al., "Cofactor Dependence of Factor Xa Incorporation into the Prothrombinase Complex" <u>The Journal of biological Chemistry</u> , (July 10, 1981) Vol. 256, No. 13 pp. 6537-6540.	
	B7	Skogen, W.F. et al., "Comparison of Coagulation Factor Xa and Des-(1-44) factor Xa in the Assembly of Prothrombinase" <u>The Journal of Biological Chemistry</u> , (February 25, 1984) Vol. 259, No. 4 pp. 2306-2310.	
	B8	Krishnaswamy, S. et al., "Prothrombinase Complex Assembly" <u>The Journal of Biological Chemistry</u> , (March 15, 1988) Vol. 263, No. 8 pp. 3823-3824.	

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		Application Number	10/712332		
		Filing Date	November 13, 2003		
		First Named Inventor	Wolf, David L.		
		Group Art Unit			
		Examiner Name			
Sheet	2	of	4	Attorney Docket Number	MPI90-002CP2DV1CNBCN3M

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and-or country where published.	T ²
	B9	Hutsen, E.J. et al., "The Active Site of Blood Coagulation Factor Xa" <u>The Journal of Biological Chemistry</u> , (September 25, 1987) Vol. 262, No. 27 pp. 12953-12961.	
	B10	Girard, T.J. et al., "Functional Significance of the Kunitz-type Inhibitory Domains of Lipoprotein-associated Coagulation Inhibitor" <u>Nature</u> , (April 6, 1989) Vol. 338, pp. 518-520	
	B11	Girard, T.J. et al., "Inhibition of Factor VIIa-tissue Factor Coagulation Activity by a Hybrid Protein" (June 15, 1990) Vol. 248, No. 4961 pp. 1421-1424.	
	B12	Dunwiddie, C. et al., "Antistatin, A Leech-derived Inhibitor of Factor Xa. Kinetic Analysis of Enzyme Inhibition and Identification of the Reactive Site" <u>The Journal of Biological Chemistry</u> , (October 5, 1989) Vol. 264, No. 28 pp. 16694-16699.	
	B13	Waxman, L. et al., "Tick Anticoagulant Peptide (TAP) is a Novel Inhibitor of Blood Coagulation Factor Xa" <u>The Journal of Biological Chemistry</u> , (May 4, 1990) Vol. 248, No. 4955 pp. 593-596.	
	B14	Bajaj, S.P. et al., "Simultaneous Purification of Bovine Prothrombin and Factor X" <u>The Journal of Biological Chemistry</u> , (November 25, 1973) Vol. 248, No. 22 pp. 7729-7741.	
	B15	Kaul, R.K. et al., "Isolation and Characterization of Human Blood-Coagulation Factor X cDNA" <u>Gene</u> , (1986) Vol. 41, Nos. 2-3 pp. 311-314.	
	B16	Bernardi, F., et al., "Partial Gene Deletion in a Family with Factor X Deficiency" <u>Blood</u> , (June 1, 1989) Vol. 73, No. 8 pp. 2123-2127.	

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		Application Number	10/712332		
		Filing Date	November 13, 2003		
		First Named Inventor	Wolf, David L.		
		Group Art Unit			
		Examiner Name			
Sheet	3	of	4	Attorney Docket Number MPI90-002CP2DV1CNBCN3M	

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and-or country where published.	T ²
	B17	Cassels, R. et al., "The Interaction of Streptokinase-Plasminogen Activator Complex, Tissue-Type Plasminogen Activator, Urokinase and Their Acylated Derivatives with Fibrin and Cyanogen Bromide Digest of Fibrinogen. Relationship to Fibrinolytic Potency in vitro" <u>The Journal of Biological Chemistry</u> , (October 15, 1987) Vol. 247, No. 2 pp. 395-400.	
	B18	Crabbe, S.J. et al., "Acylated Plasminogen-Streptokinase Activator Complex: A New Approach to Thrombolytic Therapy" <u>Pharmacotherapy</u> , (1990) Vol. 10, No. 2 pp. 115-126.	
	B19	Fair, D.S. et al., "Isolation and Characterization of the Factor X Friuli Variant" <u>Blood</u> , (June 1, 1989) Vol. 73, No. 8 pp. 2108-2116.	
	B20	Hassan, H.J. et al., "Multiple Polymorphic Sites in Factor X Locus" <u>Blood</u> , (May 1, 1988) Vol. 71, no. 5 pp. 1353-1356.	
	B21	Reddy, S.V. et al., "Molecular Characterization of Human Factor XSan Antonio" <u>Blood</u> , (October 1, 1989) Vol. 74, No. 5 pp. 1486-1490.	
	B22	Stürzebecher, J. et al., "Stable Acyl-Derivatives of Tissue-Type Plasminogen Activator" <u>Thrombosis Research</u> , (September 15, 1987) Vol. 47, No. 6 pp. 699-703.	
	B23	Watzke, H.H. et al., "Molecular Defect (Gla ⁺¹⁴ →Lys) and Its Functional Consequences in a Hereditary Factor X Deficiency (Factor X "Vorarlberg")" <u>The Journal of Biological Chemistry</u> , (July 15, 1990) Vol. 265, No. 20 pp. 11982-11989.	
	B24	Neuenschwander, P. et al., "The Use of Acetylated Factor X to Prevent Feedback Activation of Factor VIII During Factor X Activation: A Tool for Kinetic Studies" <u>Analytical Biochemistry</u> , (February 1, 1990) Vol. 184, No. 2 pp. 347-352.	

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Sheet	4	of	4	Attorney Docket Number	MPI90-002CP2DV1CNBCN3M

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	B25	Fung, M.R. et al., "Characterization of an almost Full-length cDNA Coding for Human Blood Coagulation Factor X" <u>Proceedings of the National Academy of Sciences of the United States of America</u> , (June 1985) Vol. 82, No. 11 pp. 3591-3595.	
	B26	Davie, E.W., "The Blood Coagulation Factors: Their cDNAs, Genes, and Expression" <u>Haemostasis and Thrombosis</u> , Second Edition, R.W. Colman et al., eds., (1987) J.B. Lippencott, Philadelphia, PA, Chapter 16, pp. 242-267.	
	B27	Steinberg, et al., "Activation of Factor X" <u>Haemostasis and Thrombosis</u> , Second Edition, R.W. Colman et al., eds., (1987) J.B. Lippencott, Philadelphia, PA, Chapter 7, pp. 112-119.	
	B28	Colman, et al., <u>Haemostasis and Thrombosis</u> , Second Edition, R.W. Colman et al., eds., (1987) J.B. Lippencott, Philadelphia, PA, Chapter 1, pp. 3-17.	
	B29	Fears, "Development of Anisoylated Plasminogen-Streptokinase Activator Complex from the Acyl Enzyme Concept" <u>Seminars in Thrombosis and Hemostasis</u> , (1989), Vol. 15, No. 2 pp. 129-139.	
	B29	Fears, "The Protective Effect of Acylation on the Stability of Anisoylated Plasminogen Streptokinase Activator Complex in Human Plasma" <u>Drugs 33 Supplemental 3</u> , (1987) pp. 57-63.	
	B30	Levine, "Clinical Manifestations and Therapy of Hemophilias A and B" <u>Plasma Coagulation Factors</u> , pp. 97-111.	
	B31	Nucci, M.L. et al., "the Therapeutic Value of Poly(ethylene Glycol)-Modified Proteins" <u>Advanced Drug Delivery Reviews</u> , (1991) Vol. 6, pp. 133-151.	

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